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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

REGULATION OF NEW CHEMICAL SUBSTANCES

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice
	)	Numbers:
	)	
	)	
	)	
	)	
Noramco, Incorporated	)	P90-333 and P90-335
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

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I. INTRODUCTION

Under the authority of §5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMNs") P-90-333 and P-90-335 submitted by Noramco, Incoporated ("the Company"), to take effect upon expiration of the PMN review periods.

Under §15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of §5 or any order issued under §5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to §16, and to specific enforcement and seizure pursuant to §17.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

(1) submit to EPA certain toxicity testing at least 14 weeks before manufacturing or importing a total aggregate volume combined of [ ] of the PMN substances;

(2) provide its workers personal protective equipment to prevent dermal exposure;

(3) require workers exposed via inhalation to the PMN substances in the form of a dust, mist or smoke to wear NIOSH-approved category 19C respirators;

(4) manufacture, process, and use the PMN substances for industrial use only;

(5) distribute the PMN substances outside the Company only to persons who agree to follow similar restrictions as imposed by this Order including worker protection and release restrictions and not further distribute the PMN substances until after the PMN substances have been fully reacted.

(6) label the PMN substances and comply with Material Data Safety Sheets (MSDS) and worker training provisions of the Hazard Communication Program;

(7) comply with the Release to Water provisions;

(6) maintain certain records.

III. CONTENTS OF PMN

Confidential Business Information Claims (Bracketed in the Preamble and Order):

P90-333--Production volume, Use information, Process information, and Other information.

P90-335--Chemical identity, Production volume, Use information, Process information, and Other information.

Chemical Identity:

P-90-333

Specific: 2-Propenoic acid, 2-methyl-, 2-[3-(2H-benzotriazol-2-yl)-4-hydroxyphenyl]ethyl ester.

P-90-335

Specific: [ ].

Generic: 2-Substituted benzotriazole.

Use:

P-90-333

Specific: 1. [
].

2. [
].

Generic: Stabilizer for plastics and coatings.

P90-335

Specific: 1. [
].

2. [
].

Generic: 2. Stabilizer for plastics and coatings.

Maximum 12-Month Production Volume:

P-90-333--[ ] P-90-335--[ ].

Data Submitted with PMNs:

P90-333

Acute Oral LD_{50} Study (rats): No deaths, no toxic signs at >5 g/kg.
Dermal Irritation Test (Rabbits)--Mild irritation.
Eye Irritation Test (Rabbits)--Mild irritation.
Ames Assay--Negative (with and without activation).

P90-335

Acute Oral LD_{50} Study (rats): No deaths, no toxic signs at >5 g/kg.
Dermal Irritation Test (Rabbits)--Mild irritation.
Eye Irritation Test (Rabbits)--Mild irritation.
Ames Assay--Negative (with and without activation).

IV. EPA'S ASSESSMENT OF RISK

Health Effects Summary: EPA is concerned based on analogue data for [ ] that both PMN substances may cause mutagenicity, reproductive toxicity; liver, kidney, and blood toxicity; immunotoxicity; and sensitization. For the PMN substance described in P-90-333, there is an additional concern for potential carcinogenicity based on analogy to [ ] which has been shown to cause cancer in laboratory animals.

Exposure Summary: During manufacture of P-90-333 and P-90-335 at [ ] may be exposed dermally to 18,200 mg/day and 150 mg/day through inhalation exposure for [ ]. During use of P-90-333 at up to [ ] may be exposed dermally to 18,200 mg/day and 150 mg/day via inhalation exposure for [ ] per year. During use of P-90-335 at up to [ ] may be exposed dermally to 18,200 mg/day and 150 mg/day via inhalation exposure for up to [ ] per year.

Exposure and Environmental Release Summary: During manufacture of P-90-333 at [ ], EPA estimates [ ] will be released to a publicly owned treatment works (POTW) facility, [ ] to hazardous waste landfill and [ ] to air for [ ]. During the other use of P-90-333 at up to [ ] of the PMN substance will be

landfilled. During manufacture and [ ] at [ ] will be released to a POTW. EPA estimates [ ] will be sent to hazardous waste landfill, and [ ] will be released to air for [ ] per year. During use of P-90-333 to make [ ] at up to [ ] will be landfilled.

The site where these PMN substances will be manufactured in full scale has not been built, and therefore, the Company is planning to use one of its existing sites as a pilot plant during the first year of production. The releases to surface water will occur during the manufacturing and processing of these PMN substances at the pilot plant site. Releases to water will go to the [ ] and after treatment be discharged to the [ ]. Waste streams containing a maximum amount of [ ] are expected to go to treatment. After removal during treatment, [ ] has been calculated to be released to the [ ]. EPA believes because of the tidal conditions of the [ ], these PMN substances will not create an unreasonable risk of injury to human health, via exposure through drinking water. However, EPA would have concerns if these substances were released to other surface waters where there may be exposure through drinking water. To ensure that the drinking water

exposures do not exceed an acceptable level of 80 parts per billion, the Order restricts in-stream water concentrations of the PMN substances at or below this level.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

A. EPA is unable to determine the potential for mutagenicity, reproductive, liver, kidney toxicity and blood effects from exposure to the PMN substances. EPA is also unable to determine the potential for cancer for the PMN substance reported in P-90-333. EPA therefore concludes, pursuant to §5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the health effects of the PMN substances.

B. In light of the potential risk of injury to human health posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, and the Agency's conclusion that issuing the Order will not result in any significant loss of benefits to society, EPA has concluded, pursuant to §5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances may present an unreasonable risk of injury to human health.

VI. INFORMATION REQUIRED TO EVALUATE HEALTH EFFECTS

The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of the Order in accordance with the conditions specified in the Testing section.

The following additional information would be required to evaluate the cancer effects which may be caused by the PMN substance P-90-333:

Information	Effects	Guidelines
2-year 2-species bioassay (oral)	cancer	40 CFR 798.3300

The Order does not require submission of the above information at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

CONSENT ORDER

I. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

Noramco, Incorporated ("the Company") is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the chemical substances: 2-Propenoic acid, 2-methyl-, 2-[3-(2H-benzotriazol-2-yl)-4-hydroxyphenyl]ethyl ester ("P-90-333") and [ ] ("P-90-335") ("the PMN substances") in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, except under the following conditions:

TESTING

Information on the PMN substances which reasonably supports the conclusion that the PMN substances present a substantial risk

of injury to health or the environment, and which is required to be reported pursuant to section 8(e) of the Toxic Substances Control Act (TSCA), shall be reported by the Company to EPA in accordance with EPA's section 8(e) policy statement at 43 Federal Register 11110 (March 16, 1978) as amended at 52 Federal Register 20083 (May 29, 1987). Such reports shall also reference the appropriate PMN identification number for each substance and contain a statement that the substance is subject to this Consent Order.

(b) The Company shall notify, in writing, the EPA Laboratory Data Integrity Assurance Division, Office of Compliance Monitoring (EN-342), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study intended to determine the health or environmental effects of the PMN substances, or within 15 days after the effective date of this Order, whichever is later:

1. The date when the study is scheduled to commence;

2. The name and address of the laboratory which will conduct the study; and

3. The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

(c) Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted at the time the study is initiated. Before starting to conduct the above referenced studies, the Company must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) (e.g., 40 CFR 797 or 798) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

(d) The Company is prohibited from manufacturing or importing the PMN substances beyond the following combined aggregate manufacture and import volume ("the production limit"), unless the Company conducts the following studies on the PMN substances and submits all final reports and underlying data in accordance with the conditions specified in this Testing section:

Production Limit	Study	Guideline
[ ]	90-day Subchronic (Gavage) (P90-333)	40 CFR 798.2650
	In Vitro Gene Mutation Assay in Mouse Lymphoma L5178Y (P90-333 and P90-335)	40 CFR 798.5300
	2-Generation Reproduction Study (gavage) (P90-333)	40 CFR 798.4700

Production Limit	Study	Guideline (Contd.)
	Dermal Sensitization (P90-333; if positive, also test P90-335).	40 CFR 798.4100

(e) The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production limit. If the Company does not submit the report and data to EPA at least 14 weeks before reaching the applicable production limit, the Company may not exceed the applicable production limit until EPA completes its review of the report and data and notifies the Company, in writing, that the Company may exceed the production limit.

(f) The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substances beyond the applicable production

limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company.

(h) (1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may continue to manufacture and import the PMN substances beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time

for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) (1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substances beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of

scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture and import the PMN substances beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) (1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order,

the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and/or disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and/or disposal of the PMN substances.

(k) Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part III. of this Consent Order.

PROTECTION IN THE WORKPLACE

(a) During manufacturing, processing, and use of the PMN substances at any site controlled by the Company, the Company must establish a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the PMN substances through direct handling of the substances or through contact with equipment on which the substances may exist, or because the substances become airborne in a form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substances in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 29 CFR 1910.133.

(2) The Company is able to demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure to the PMN substances during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substances alone and in likely combination with other chemical substances in the work area.

(3) Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substances in the form listed in subparagraph (a)(5) of this section, is provided with, and is required to wear, at a minimum, a NIOSH-approved

respirator from one of the categories listed in subparagraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR Part 11.

(4) The following NIOSH-approved respirators meet the minimum requirements for subparagraph (a)(3) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(iii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous mode and equipped with a hood or helmet or tight-fitting facepiece.

(5) The following forms of airborne chemical substances are listed for subparagraphs (a)(1) and (3) of this section:

(i) Dust.

(ii) Mist.

(iii) Smoke.

(b) If the PMN substances are present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of either PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if

paragraph (g) of the Hazard Communication Program section of this Order identifies cancer as a potential human health hazard of the PMN substance. This exemption does not apply if the Company has reason to believe that during intended use or processing in the work area, either PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

HAZARD COMMUNICATION PROGRAM

(a) Written hazard communication program. The Company shall develop and implement a written hazard communication program for the PMN substances in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration ("OSHA") Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list containing the identity of each PMN substance. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the MSDSs for the substances required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) Significant New Use Rule ("SNUR") at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substances (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substances contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substances in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substances while in the Company's workplace.

(b) Labeling. (1) The Company shall ensure that every container of each PMN substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified in paragraph (g) of this section or by the Company, for the PMN substance.

(B) The identities by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified in paragraph (g) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substances are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substances obtained from persons outside the Company unless the container is immediately relabeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of each PMN substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substances in combination with any other substances that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(c) Material Safety Data Sheets. (1) The Company must obtain or develop an MSDS for each of the PMN substances.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common names are claimed confidential, a generic chemical name will be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (g) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required under the Protection in the Workplace section of this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing either PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substances or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured, imported, processed, or used in the

Company's workplace, the Company must add the new information to the MSDS before the PMN substances are reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substances from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of each MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substances and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee information and training. The Company must ensure that employees are provided with information and training on the PMN substances. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substances and whenever the PMN substances are introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substances are present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substances in or from an employee's work area (such as monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the PMN substances as specified in paragraph (g) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substances, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substances, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDSs required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low concentrations in mixtures. If the PMN substances are present in the work area only as a mixture, the Company is exempt from the provisions of this section if the concentration of either PMN substance in the mixture does not exceed 1.0 percent or greater by weight or volume, or 0.1 percent or greater by weight or volume if paragraph (g) of this section identifies cancer as a potential human health hazard of the PMN substance. However, this exemption does not apply if the Company has reason

to believe that during intended use or processing in the work area, either PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever is applicable.

(f) Existing hazard communication program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human health, environmental hazard, exposure, and precautionary statements. The following human health and environmental hazard and precautionary statements shall appear on each label for both PMN substances as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. These substances may cause:

(i) skin irritation.

(ii) respiratory complications.

(iii) internal organ effects.

(iv) reproductive effects.

(v) immune system effects.

(2) Human hazard precautionary statements. When using these substances:

(i) avoid skin contact.

(ii) avoid breathing the substance.

(iii) use respiratory protection.

(iv) use skin protection.

(3) In addition, for PMN substance P-90-333, the MSDS must contain the following precautionary statement:

(i) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals. Avoid skin contact. When using this substance, use skin protection. Use respiratory protection when there is a reasonable likelihood of exposure in the work area from a dust, mist or smoke from spray applications.

(4) Each human and environmental hazard and precautionary statement prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a) (1) The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person.

(2) The restrictions contained in subparagraph (a)(1) shall expire 75 days after promulgation of a final SNUR governing the PMN substances under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, the restrictions contained in subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) If EPA promulgates a final SNUR for the PMN substances and the restrictions contained in subparagraph (a)(1) expire in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR.

USE

(a) The Company shall not use the PMN substances:

(1) For non-industrial applications;

DISTRIBUTION

(a) The Company shall distribute the PMN substances outside the Company only to a person who agrees in writing to:

(1) Not further distribute the PMN substances to any other person, other than for disposal, until after the PMN substances have been completely reacted (cured).

(2) Comply with the same worker exposure restrictions, if any, required of the Company in the Protection in the Workplace section of this Order.

(3) Comply with the same environmental release restrictions, if any, required of the Company in the Disposal and Release to Water sections of this Order.

(b) If, at any time after commencing distribution in commerce of the PMN substances, the Company has knowledge that a recipient of the substances have failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, the Company shall cease supplying the substances to that recipient, unless the recipient is in compliance with a SNUR for the PMN substances, or unless the Company is able to document each of the following:

(1) That the Company has within 5 working days notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (a) of this Distribution section and will comply with those terms.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (b)(2) of this Distribution section, the Company has knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (a) of this Distribution section, the Company shall cease supplying the PMN substances to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(c) (1) The restrictions contained in this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substances under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, the restrictions contained in this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) If EPA promulgates a final SNUR for the PMN substances and the restrictions contained in this Distribution section expire in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substances of the existence of the SNUR.

RELEASE TO WATER

(a) The Company is prohibited from any predictable or purposeful release of the PMN substances or any waste stream from manufacturing and use of the substances:

(1) (i) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/ site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds 80 parts per billion, when calculated using the methods described in 40 CFR 721.91. However, if the waste stream containing the PMN substances will be treated using biological treatment (activated sludge or equivalent) plus clarification, then the amount of the PMN substances reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than 75 percent removal efficiency may be attributed to such treatment.

(ii) In lieu of calculating the quotient in subparagraph (4)(i), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Company of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefor.

II. RECORDKEEPING

(a) The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

(2) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substances, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(3) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;

(4) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substances;

(5) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(6) Copies of labels required under the Hazard Communication Program section of this Order;

(7) Copies of material safety data sheets required by the Hazard Communication Program section of this Order;

(8) Records documenting compliance with any applicable manufacturing, use, and distribution restrictions in the Manufacturing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(9) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order.

III. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health effects of, or human exposure to, the PMN substances, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

IV. EFFECT OF CONSENT ORDER

By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, does not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

Date OCT 9 1990

Linda J. Fisher
Assistant Administrator
for Pesticides and
Toxic Substances

Date 10/24/90

Name:

Title:

Company: Noramco, Inc.

ATTACHMENT A

DEFINITIONS

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"PMN substance" means the chemical substance described in the Premanufacture notice or notices submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although

developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where a chemical substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.